

IN THE CLAIMS:

Please amend claim 1, cancel claim 5 without prejudice or disclaimer, and add new claims 6-14, as follows:

1. (AMENDED) A process for detecting or determining a C-peptide-containing impurity in a sample of recombinantly produced human insulin or a derivative thereof, by a non-radioactive assay, comprising the steps:

- (a) preparing a sample of recombinantly produced human insulin or a derivative thereof;
- (b) mixing the samples with dilution buffer;
- (c) adding a tracer to mixture (b);
- (d) adding antibody specific for the C-peptide impurity to mixture (c);
- (e) adding a C-peptide second antibody bead having at least one label to mixture (d); and
- (f) detecting or determining the presence of the C-peptide-containing impurity.

6. (NEW) The process according to claim 1, wherein the antibody specific for the C-peptide impurity additionally recognizes at least one model compound chosen from preproinsulin, reduced human insulin, alkylated human insulin, human insulin cleaved with endoproteinase, Lys(B3)-Glu(B29)-human insulin C-peptide, and Lys(B3)-Glu(B29)-human insulin preproinsulin.

7. (NEW) The process according to claim 1, wherein the antibody specific for the C-peptide impurity recognizes both C-peptide and preproinsulin with nearly the same affinity.

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8. (NEW) The process according to claim 1, wherein the tracer is chemiluminescent.
9. (NEW) The process according to claim 8, wherein the tracer comprises an acridinium ester moiety.
10. (NEW) The process according to claim 1, wherein the presence of about 1 mg/mL human insulin does not interfere with the binding of the antibody specific for the C-peptide impurity.
11. (NEW) The process according to claim 1, wherein the antibody specific for the C-peptide impurity is obtained by immunizing a mammal with a purified insulin C-peptide.
12. (NEW) The process according to claim 11, wherein the mammal is a sheep.
13. (NEW) The process according to claim 11, wherein the purified insulin C-peptide is monkey C-peptide.
14. (NEW) The process according to claim 11, wherein the purified insulin C-peptide is human C-peptide.

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